

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|   |  |  |                       |
|---|--|--|-----------------------|
| Applicant's or agent's file reference<br>03op133p   | <b>FOR FURTHER ACTION</b>  |  | See Form PCT/IPEA/416 |
| International application No.<br><b>PCT/KR2004/000092</b>   | International filing date(day/month/year)<br><b>19 JANUARY 2004 (19.01.2004)</b> | Priority date (day/month/year)<br>23 JANUARY 2003 (23.01.2003) |                       |
| International Patent Classification (IPC) or national classification and IPC<br><br><b>IPC7 A61K 9/16</b> |  |  |                       |
| Applicant<br><br><b>AMOREPACIFIC CORPORATION et al</b>  |  |  |                       |

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
  - ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_ containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:
  - ☒ Box No. I Basis of the report
  - ☐ Box No. II Priority
  - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Box No. IV Lack of unity of invention
  - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Box No. VI Certain documents cited
  - ☐ Box No. VII Certain defects in the international application
  - ☐ Box No. VIII Certain observations on the international application

|  |   |
|--|---|
| Date of submission of the demand<br><br><b>23 JULY 2004 (23.07.2004)</b>   | Date of completion of this report<br><br>27 OCTOBER 2004 (27.10.2004)   |
| Name and mailing address of the IPEA/KR<br> Korean Intellectual Property Office<br>920 Dunsan-dong, Seo-gu, Daejeon 302-701,<br>Republic of Korea<br>Facsimile No. 82-42-472-7140 | Authorized officer<br><br>Yoon, Kyung Ae<br><br>Telephone No. 82-42-481-5605<br> |

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/000092

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_ which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished

- ☐ the description:  
pages \_\_\_\_\_ as originally filed/furnished  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☐ the claims:  
pages \_\_\_\_\_ as originally filed/furnished  
pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☐ the drawings:  
pages \_\_\_\_\_ as originally filed/furnished  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheet \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/000092

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Statement

|                               |        |      |     |
|-------------------------------|--------|------|-----|
| Novelty (N)                   | Claims | 1-13 | YES |
|                               | Claims | none | NO  |
| Inventive step (IS)           | Claims | 1-13 | YES |
|                               | Claims | none | NO  |
| Industrial applicability (IA) | Claims | 1-13 | YES |
|                               | Claims | none | NO  |

## 2. Citations and explanations (Rule 70.7)

The present invention relates to sustained-release preparations characterized by being prepared from double granules which are obtained by primary granulation of a drug according to melt granulation using hydrophobic release-delaying additives, and then by secondary granulation of the obtained granules according to wet granulation using hydrophobic wet-granulation material.

The following documents have been considered for the purpose of this report:

D1 = WO 99/47128 A1 (23. 09. 1999)

D2 = US 5807583 A (15. 09. 1998)

D3 = EP 1125586 A1 (22. 08. 2001)

D4 = US 2002/102302 A1 (01. 08. 2002)

D5 = US 5451409 A (19. 09. 1995)

D1 discloses a biphasic controlled release delivery system for high solubility pharmaceuticals, which includes an inner solid particulate phase and an outer solid continuous phase.

D2 discloses a process for manufacturing sustained release pellets comprising pelletizing a mixture containing a drug in finely divided form and a water-insoluble wax-like binder.

D3 discloses sustained release particles comprising a drug-containing core substance coated with a mixed coating of a hydrophobic organic compound and water-insoluble polymer, which prevents sticking during compression molding when producing tablets.

D4 describes a stabilized sustained release tramadol tablet containing a hydrophobic material which comprises a wax-like substance.

D5 describes a sustained release matrix and oral dosage form comprising a homogeneous matrix formed from a wet granulation containing a medicament and a polymer blend of HEC and HPC.

(Continued in Supplemental Box)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V.

**1. Novelty**

None of D1 to D5 relates to sustained-release double granule preparations obtained by primary melt granulation and secondary wet granulation as claimed in the present claims 1 to 13.

Therefore, the subject matter of claims 1-13 can be regarded as novel under PCT Article 33(2).

**2. Inventive Step**

None of the above-mentioned prior art documents teaches or fairly suggests sustained-release preparations prepared from double granules which are obtained by primary melt granulation and secondary wet granulation using hydrophobic materials such as waxes and fatty acids, nor improved properties of said preparations characterized by minimizing the amount of hydrophobic additives for imparting sustained-releasing property and eliminating an adhesion phenomenon of granules occurring during the tablet preparation. The prior art documents merely refer to sustained-release preparations obtained by either melt or wet granulation. Therefore, the subject matter of claims 1-13 is considered to involve an inventive step under PCT Article 33(3).

**3. Industrial Applicability**

The subject matter of claims 1-13 is considered to be industrially applicable under PCT Article 33(4).